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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/691,069

10/21/2003

David A. Hinds

100/1045-10

9284

31662

7590

10/26/2006

PERLEGEN SCIENCES, INC.  
LEGAL DEPARTMENT  
2021 STIERLIN COURT  
MOUNTAIN VIEW, CA 94043

EXAMINER

CLOW, LORI A

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/691,069

Applicant(s)

HINDS, DAVID A.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 9-14, 19-22 and 26-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8, 15-18 and 23-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 11/25/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

Applicant's election with traverse of Group I, claims 1-8, 15-18, and 23-25 in the reply filed on 11 August 2006 is acknowledged. The traversal is on the ground(s) that any search on the claims of one group must necessarily include prior art that is most relevant to the claims of the other group. This is not found persuasive because as was stated in the requirement for restriction, the related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions have a different mode of operation, function and effect.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-28 are pending. Claims 1-8, 15-18 and 23-25 are examined herein. Claims 9-14, 19-22 and 26-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 11 August 2006.

#### **Information Disclosure Statement**

The Information Disclosure Statement filed 11/25/03 has been partially considered. Reference 2 has not been considered, as it lacks a publication date. A signed copy of PTO form 1449 is included with this Office Action.

**Drawings**

The drawings submitted 21 October 2003 are accepted.

**Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 7, 8, and 15-18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1, 3, 7, and 8 are directed to a computer implemented method for analyzing a case-control genetic association study including providing a spreadsheet, programming software, inputting values and determining the study's power to detect a difference in distribution of observed allele frequency, which does not recite either a physical transformation of matter or a concrete, tangible, and useful result. No description of providing a spreadsheet, programming software etc... is provided in the specification such these would be interpreted as physical steps, therefore the claimed method does not result in a physical transformation. Where a claimed method does not result in a physical transformation of matter, the claims may be statutory if they recite a concrete, tangible, and useful result. However, no actual concrete result is recited in the claims, nor is any useful result "produced" in a tangible form useful to one skilled in the art.

Claims 15-18 are directed to a computer program product comprising a computer-readable medium. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely

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claiming nonfunctional descriptive material, i.e., abstract ideas, stored in a computer-readable medium, in a computer, or on an electromagnetic carrier signal does not make it statutory. See *Diehr*, 450 U.S. at 185-86, 209 USPQ at 8 (noting that the claims for an algorithm in *Benson* were unpatentable as abstract ideas because “[t]he sole practical application of the algorithm was in connection with the programming of a general purpose computer.”) Such a result would exalt form over substance. In *re Saker*, 588 F.2d 1330, 1333, 200 USPQ 132, 137 (CCPA 1978)... In the instant case, the medium is recited as a carrier wave (claim 16) and the specification teaches that the medium may be a carrier wave. Therefore, the claims are directed to non-statutory subject matter.

For an updated discussion of statutory discussions with regard to the above, Applicant is invited to view the Guidelines for Patent Eligible Subject Matter at 1300 OG 142, November 22, 2005.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8, 15-18, and 23-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, “programming the spreadsheet software”. There is insufficient antecedent basis in the claim for “the spreadsheet software”, as only “spreadsheet program” was recited in step (a). Clarification is requested.

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Claim 1 recites, “inputting to the spreadsheet program values for parameters defining the genetic association study”. It is unclear if this “genetic association study” is the same as the “case-control genetic association study” recited in the preamble or if this is a different study. Clarification is requested.

Claim 1 recites, “inputting to the spreadsheet program values for parameters defining the genetic association study”. It is unclear what parameters are intended for input such that they define a genetic association study. Are the parameters intended to be the different alleles or some other parameter? Clarification is requested.

Claim 1 recites, “determining, using the power algorithm, the study’s power to detect a significant difference in distribution of observed allele frequency in cases and controls”. It is unclear what the relationship of this step is to steps (a) to (c), as no cases and controls were recited nor were frequencies recited. Clarification is requested.

Claims 7 and 8 recite, “wherein the parameters defining the genetic association study comprise trait value thresholds used to define case and controls”. It is unclear if the “case” is referring to “cases” recited in step (d) or if it is referring to a separate “case”. Perhaps this is a typographical error and applicant intends the claim to read “used to define cases and control”. Clarification is requested.

Claim 15 recites, “receiving to the spreadsheet program values for parameters defining the genetic association study”. It is unclear if this “genetic association study” is the same as the “case-control genetic association study” recited in the preamble or if this is a different study. Clarification is requested.

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Claim 15 recites, “receiving to the spreadsheet program values for parameters defining the genetic association study”. It is unclear what parameters are intended for input such that they define a genetic association study. Are the parameters intended to be the different alleles or some other parameter? Clarification is requested.

Claim 15 recites, “determining, using the power algorithm, the study’s power to detect a significant difference in distribution of observed allele frequency in cases and controls”. It is unclear what the relationship of this step is to steps (a) to (b), as no cases and controls were recited nor were frequencies recited. Clarification is requested.

Claims 17 and 18 recite, “wherein the parameters defining the genetic association study comprise trait value thresholds used to define case and controls”. It is unclear if the “case” is referring to “cases” recited in step (c) or if it is referring to a separate “case”. Perhaps this is a typographical error and applicant intends the claim to read “used to define cases and control”. Clarification is requested.

Claim 23 recites, “receive program values for parameters defining the genetic association study”. It is unclear if this “genetic association study” is the same as the “case-control genetic association study” recited in the preamble or if this is a different study. Clarification is requested.

Claim 23 recites, “determine, using the power algorithm, the study’s power to detect a significant difference in distribution of observed allele frequency in cases and controls”. It is unclear what the relationship of this step is the rest of the claim, as no cases and controls were recited nor were frequencies recited. Clarification is requested.

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Claims 24 and 25 recite, "wherein the parameters defining the genetic association study comprise trait value thresholds used to define case and controls". It is unclear if the "case" is referring to "cases" recited in claim 23 or if it is referring to a separate "case". Perhaps this is a typographical error and applicant intends the claim to read "used to define cases and control". Clarification is requested.

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 15-16, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Risch et al. (Genome Research (1998) Vol. 8, pages 1273-1288), in view of Taylor (PC Magazine (1987) Issue 12, pages 103-111).



The instant claims are drawn to a computer implemented method, program and computer system for analyzing a case-control genetic association study.

Risch et al. teach a method for detecting linkage disequilibrium of a marker with a disease susceptibility locus to evaluate the relative power of different study designs using statistics (page 1273, abstract), claim 1.

In further regard to claim 1, Risch teaches cases and controls (abstract and page 1274, column 1). Risch further teaches a genetic model employing a power algorithm for genetic association of allele frequency (page 1275, column 2 to page 1286).

In regard to claim 3, Risch teaches a plurality of inputs (pages 1276-1286).

Risch et al. do not teach providing a spreadsheet for the analysis or displaying in graphical form the power to detect distribution differences or the actual software/computer to run the method (claims 15-16 and 23). However, Taylor teaches the spreadsheet program Excel in which design of user specific functions are possible using the macro function (page 2). Further, display formats are versatile and include charts and graphs (page 5) in various forms, as in claims 2, and 4-6.

It would have been prima facie obvious to one of ordinary skill in the art to program a spreadsheet, such as Excel, with a power algorithm, as taught by Risch for use in implementing a method and generating software on a computer to analyze a case study. One would have been motivated to do so because Excel was designed for user defined macro input to run user defined applications (page 6) in statistical analysis.

No claims are allowed.

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**Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

October 24, 2006

Lori A. Clow, Ph.D.

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*Lori A. Clow*

*Patent Examiner*